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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,898	01/18/2002	Wolfgang A. Renner	1700.0190005/BJD/SJE	7794
26111	7590	04/12/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			MOSHER, MARY	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/050,898	Applicant(s) RENNER ET AL	
	Examiner Mary E. Mosher, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,11-22,51 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,10,23-50 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date : <u>10/29/03.</u> | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet.</u> |

Continuation of Attachment(s) 6). Other: IDS 9/15/03, 8/19/03, 4/08/03, 11/27/02, 11/26/02, 11/20/02.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II, claims 1-17, 23-50, 52, species RNA phage Q-beta, linkers GGC or GGC-NH₂, crosslinker SMPH, SEQ ID NO:367, in the reply filed on 1/25/2006 is acknowledged. The traversal is on the ground(s) that the groups are commonly classified. This is not found persuasive because the various species require burdensome divergent search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 18-22, 51, 53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/25/2006. Claims 8, 9, 11-17 are withdrawn from further consideration, as being drawn to a nonelected species of particle.

Claim Rejections - 35 USC § 112

Claims 1-7, 10, 23-50, and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection concerns the "how-to-use" aspect of enablement. The specification suggests using the claimed amyloid-beta array for therapeutic treatment of Alzheimer disease, using the array to induce a self-specific immune response against amyloid. However, human clinical studies on immunization

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with amyloid-beta have been halted, since the immunization resulted in meningoencephalitis and other adverse effects. See the reviews by Dodart et al, McGeer et al, and Janus as evidence. Animal model studies similar to the ones cited by applicants did not predict the human response. Considering the absence of guidance in the specification, the absence of working examples, the unpredictability in the art, and the conclusions by later workers that substantial additional experimentation will be required for success of an immunogenic therapy for Alzheimer's disease, it is concluded that undue experimentation would be required to use the invention in the manner suggested in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 6, 36, 42-46, 50, 52 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Solomon et al US 2002/0052311. See e.g. Examples 10-14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 23, are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Solomon et al US 2002/0052311 and Chackerian et al (PNAS 96:2373-2378, 1999). Solomon teaches an RNA phage displaying an epitope of amyloid beta polypeptide for the purpose of producing an autoimmune reaction to amyloid deposits. These claims differ from Solomon in that they require a virus-like particle rather than an RNA phage. However, Chackerian et al teaches that virus-like particles can be used to induce an autoimmune reaction. Therefore, use of a virus-like particle to present an amyloid beta polypeptide is seen as prima facie obvious, absent unexpected results.

Claims 3, 7, 10, 23-35, 37, 39-41, 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Solomon et al US 2002/0052311 and Mastico et al US 5698424. These claims differ from Solomon in that they require a

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phage-like particle instead of a phage, and in that they require a nonpeptide link between the particle and the peptide. However, Mastico teaches self-assembly of a recombinant phage-like particle, and chemical crosslinking of immunogenic material to the particle. Therefore, use of a phage-like particle and common forms of chemical crosslinker are seen as prima facie obvious, absent unexpected results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Mary Mosher". The signature is fluid and cursive, with the first name "Mary" and the last name "Mosher" clearly distinguishable.

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER